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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/599,310	10/20/2008	Alexei M. Voloshin	STAN-353	6761

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Stanford University Office of Technology Licensing
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Suite 200
East Palo Alto, CA 94303

EXAMINER

KIM, YOUNG J

ART UNIT	PAPER NUMBER
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1637

MAIL DATE	DELIVERY MODE
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10/11/2011

PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary

Application No.

10/599,310

Applicant(s)

VOLOSHIN ET AL.

Examiner

Young J. Kim

Art Unit

1637

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☐ Responsive to communication(s) filed on ____.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ An election was made by the applicant in response to a restriction requirement set forth during the interview on ____; the restriction requirement and election have been incorporated into this action.
- 4) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 5) ☒ Claim(s) 1,3,5,6,13,16-20 and 22-24 is/are pending in the application.
- 5a) Of the above claim(s) ____ is/are withdrawn from consideration.
- 6) ☐ Claim(s) ____ is/are allowed.
- 7) ☒ Claim(s) 1,3,5,6,13,16-20 and 22-24 is/are rejected.
- 8) ☐ Claim(s) ____ is/are objected to.
- 9) ☐ Claim(s) ____ are subject to restriction and/or election requirement.

Application Papers

- 10) ☐ The specification is objected to by the Examiner.
- 11) ☐ The drawing(s) filed on ____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 12) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 13) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
- ☐ Certified copies of the priority documents have been received.
 - ☐ Certified copies of the priority documents have been received in Application No. ____.
 - ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- 1) ☒ Notice of References Cited (PTO-302)
- 2) ☐ Notice of Draftperson's Patent Drawing Review (PTO-948)
- 3) ☐ Information Disclosure Statement(s) (PTO/SB/08)
Paper No(s)/Mail Date ____.
- 4) ☐ Interview Summary (PTO-413)
Paper No(s)/Mail Date ____.
- 5) ☐ Notice of Informal Patent Application
- 6) ☐ Other: ____.

Art Unit: 1637

DETAILED ACTION

The present Office Action is responsive to the Amendment received on July 14, 2011.

Preliminary Remark

The present Office communication contains at least one rejection which is not necessitated by the Amendment received on July 20, 2011, and is therefore made, **Non-Final**.

Claim Rejections - 35 USC § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(e) the invention was described in (1) an application for patent, published under section 122(b), by another filed in the United States before the invention by the applicant for patent or (2) a patent granted on an application for patent by another filed in the United States before the invention by the applicant for patent, except that an international application filed under the treaty defined in section 351(a) shall have the effects for purposes of this subsection of an application filed in the United States only if the international application designated the United States and was published under Article 21(2) of such treaty in the English language.

Claims 1, 3, 5, 6, 13, 16, 17, 19, 20, and 22-24 are rejected under 35 U.S.C. 102(e) as being anticipated by Calhoun et al. (US 2007/0154983 A1, published July 5, 2007, priority November 20, 2003).

The applied reference has a common inventor (James Robert Swartz) with the instant application. Based upon the earlier effective U.S. filing date of the reference, it constitutes prior art under 35 U.S.C. 102(e). This rejection under 35 U.S.C. 102(e) might be overcome either by a showing under 37 CFR 1.132 that any invention disclosed but not claimed in the reference was derived from the inventor of this application and is thus not the invention “by another,” or by an appropriate showing under 37 CFR 1.131.

Art Unit: 1637

Calhoun et al. disclose a reaction mixture for cell-free translation of mRNA to produce polypeptides, comprising:

- (a) a cell extract ("0.24 volumes of S30 extract", section [0066]);
- (b) mRNA ("combined transcription-translation reaction," which would necessarily have an mRNA present in the mixture, section [0066]);
- (c) monomers for the polypeptide to be synthesized ("2 mM each of 20 unlabeled amino acids ..." section [0066]); and
- (d) such co-factors, enzymes and other reagents that are necessary for the synthesis (see section [0066] and [0067] for the list); and
- (e) an anti-foam agent other than a detergent at a concentration of at least 0.0007%, and not more than 0.007% by weight ("[t]o demonstrate the utility of the new glutamate and phosphate system, 1 mL jacketed bubble column reactions were performed. Combined transcription and translation reaction ... were carried out ... using the Cytomin conditions ... except that the reaction was supplemented with 0.007% (v/v) Sigma 0-30 antifoam...was used to control foaming.", section [0072]), thereby clearly anticipating claim 16.

With regard to claims 22-24, since Applicants are using the same reagent (see Table 1, page 10 of the instant specification), the limitation is assumed to be met.

With regard to claims 1, 13, and 17, Calhoun et al. employ the above reagent mix in an *in vitro* protein synthesis (see section [0072]).

With regard to claim 3, since transcription and translation is occurring the same system, mRNA would necessarily be made from a DNA template.

With regard to claim 5, the reaction size is 15 μ L (see Table 3).

Art Unit: 1637

With regard to claim 6, since Calhoun et al. employ the same reagent as that of the instant claims, the yield is deemed to be identical.

With regard to claims 19 and 20, the artisans disclose that the method was conducted in bubble column reactions (section [0072]).

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

Claim 18 is rejected under 35 U.S.C. 103(a) as being obvious over Calhoun et al. (US 2007/0154983 A1, published July 5, 2007, priority November 20, 2003).

The applied reference has a common inventor (James Robert Swartz) with the instant application. Based upon the earlier effective U.S. filing date of the reference, it constitutes prior art only under 35 U.S.C. 102(e). This rejection under 35 U.S.C. 103(a) might be overcome by: (1) a showing under 37 CFR 1.132 that any invention disclosed but not claimed in the reference was derived from the inventor of this application and is thus not an invention “by another”; (2) a showing of a date of invention for the claimed subject matter of the application which corresponds to subject matter disclosed but not claimed in the reference, prior to the effective U.S. filing date of the reference under 37 CFR 1.131; or (3) an oath or declaration under 37 CFR 1.130 stating that the application and reference are currently owned by the same party and that the inventor named in the application is the prior inventor under 35 U.S.C. 104, together with a terminal disclaimer in

Art Unit: 1637

accordance with 37 CFR 1.321(c). This rejection might also be overcome by showing that the reference is disqualified under 35 U.S.C. 103(c) as prior art in a rejection under 35 U.S.C. 103(a). See MPEP § 706.02(l)(1) and § 706.02(l)(2).

The teachings of Calhoun et al. have already been discussed above.

The artisans do not explicitly disclose that the reaction mixture volume should be greater than 100 µl (claim 18).

It would have been *prima facie* obvious to one of ordinary skill in the art at the time the invention was made to apply the teachings of Calhoun et al. with the knowledge and practice of the art, so as to arrive at the invention as claimed because Calhoun et al. already provided for a method of *in vitro* transcription reaction with improved protein yield wherein the method employs the use of an antifoaming agent. Having provided with such teachings, one of ordinary skill in the art would have been motivated to determine the optimal reaction conditions, including the volume of the reaction for optimizing the protein yield conditions, the determination of which would have required routine optimization.

Therefore, the invention as claimed is deemed *prima facie* obvious over the cited reference.

Conclusion

No claims are allowed.

Inquiries

Any inquiry concerning this communication or earlier communications from the Examiner should be directed to Young J. Kim whose telephone number is (571) 272-0785. The Examiner is on flex-time schedule and can best be reached from 6:00 a.m. to 2:30 p.m (M-F). The Examiner can also be reached via e-mail to Young.Kim@uspto.gov. However, the office cannot guarantee security through the e-mail system nor should official papers be transmitted through this route.

Art Unit: 1637

If attempts to reach the Examiner by telephone are unsuccessful, the Examiner's supervisor, Gary Benzion, can be reached at (571) 272-0782.

Papers related to this application may be submitted to Art Unit 1637 by facsimile transmission. The faxing of such papers must conform with the notice published in the Official Gazette, 1156 OG 61 (November 16, 1993) and 1157 OG 94 (December 28, 1993) (see 37 CFR 1.6(d)). NOTE: If applicant does submit a paper by FAX, the original copy should be retained by applicant or applicant's representative. NO DUPLICATE COPIES SHOULD BE SUBMITTED, so as to avoid the processing of duplicate papers in the Office. All official documents must be sent to the Official Tech Center Fax number: (571) 273-8300. For Unofficial documents, faxes can be sent directly to the Examiner at (571) 273-0785. Any inquiry of a general nature or relating to the status of this application should be directed to the Group receptionist whose telephone number is (571) 272-1600.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/Young J. Kim/
Primary Examiner
Art Unit 1637
10/7/2011

/YJK/